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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TSAY, MARSHA M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,115	Applicant(s) MORGAN ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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This Office action is in response to Applicants' remarks received December 2, 2008.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2, 7, 9 are canceled. Claims 1, 3-6, 8, 10-21 are pending and currently under examination.

Priority: The request for priority to UK 0303999.7, filed February 21, 2003, is acknowledged.

Objections and Rejections

Claim 1 is objected to because of the following informalities: in claim 1, the phrase “having a fat content” should be punctuated by commas because as currently written, it appears as if the fat content is made from the extrudable gel. Additionally, lines 6-10 of claim 1 do not flow in a manner that clearly defines the collagen content. Claim 1, lines 6-10 recite that the collagen content consists essentially of sow collagen, wherein any non-porcine collagen derived from sheep, poultry, birds and/or fish is present in an amount of less than 10% by weight, and wherein any non-sow porcine collagen is derived from young pigs and is present in a ratio of collagen derived from young pigs to collagen derived from sows (i.e. sow collagen) is in the range of 0:100 to 10:90 by weight. The claim appears to specify that non-sow porcine collagen has to be present and is derived from young pigs in the ratios as recited; however, the lines above recite that non-porcine collagen can also be derived from the species recited and are present in an

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amount less than 10%. The claim is confusing because since there is no lower limit to the 10%, the claim does not require that non-porcine collagen be present or if it is, it can be present at 10% by weight; however, the claim goes on to further recite that non-sow porcine collagen has to be present in another distinct quantity. The different types of collagen present should be rewritten or else presented as dependent claims of independent claim 1 for clarity.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8, 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 20050031741; previously cited) in view of Eckmayer et al. (US 6482240; IDS, previously cited). Morgan et al. teach collagen casings or film made from an extrudable collagen gel, wherein the collagen is porcine collagen (p. 1 [0001]-[0002]). In working examples 3-4, Morgan et al. teach a porcine collagen film was prepared from an extrudable porcine collagen gel, having a weight ratio of collagen to fat of around 30:1 (p. 4 [0059]; claims 1, 4-6, 17). The table in paragraph [0062]) indicates a fat percentage of 0.31% and 0.19% for examples 3 and 4, respectively (p. 4; claims 1-3). The porcine collagen casing in example 20 comprises 6.0% of caprine (goat) collagen on a dry weight basis (p. 12; claims 7-8). Morgan et al. also teach that the collagen properties of the casings can be varied by mixing collagen derived from young pigs (4 mos. old) and older pigs (3 yrs. old) in ratios of 0:100 to 100:0 (p. 2 [0019];

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claim 9). In example 12, Morgan et al. teach a porcine collagen casing with a humectant (i.e. glycerol) level of 21.5% on a dry weight basis (p. 8-9; claims 13-14). The collagen casing in example 16 comprises propylene glycol alginate (p. 10; claims 10-12). In example 9, Morgan et al. teach the porcine casing further comprises glutaraldehyde (p. 6 [0128]; claim 15). Also, the collagen casing has a collagen solids content of 7% (p. 13-14; claim 16). In example 1-4, Morgan et al. teach the porcine collagen casings were used to make sausages (p. 3-4; claim 21). The casing of Morgan et al. can also be used to make edible string and/or netting (p. 2 [0022]; claim 18). Further, Morgan et al. teach a method of producing an extruded porcine collagen film from sow collagen comprising soaking sow skins, removing fat by a fleshing machine (p. 3 [0032]), forming an extrudable gel from the sow skins by blending and disintegrating porcine skin (p. 3 [0039]), and extruding the gel to form a casing (p. 3 [0040]-[0045]) (claims 19-20). Morgan et al. do not explicitly teach the collagen casing is in another film besides a tube.

Eckmayer et al. teach collagen membranes formed from porcine skins are enzymatically defatted, ground into a gel-like mass, extruded and dried into a collagen membrane (col. 2 lines 59-67). Eckmayer et al. teach the collagen membranes can be formulated as films (col. 1 lines 13). In example 1, Eckmayer et al. teach a method of producing a porcine collagen film comprising defatting porcine skins by mechanical means (col. 4 line 64), forming a gel-like fluid mass (col. 8 lines 17), and extruding the gel to form a film and/or membrane (col. 10 line 1). Eckmayer et al. teach the collagen film can be used as a net to wrap around ham (col. 12 lines 16-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Morgan et al. by extruding the collagen gel to form a film

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as suggested by Eckmayer et al. instead of as a thin-walled tube (claims 1, 3-6, 8, 10-21). The motivation to do is given by Eckmayer et al., which disclose that collagen membranes can be extruded from collagen gels and formed into a film to wrap around a food product. It would be reasonable for one of ordinary skill to recognize that a collagen membrane formed into a film can have broader applications than a collagen membrane formed into a tube shape, i.e. casing.

Although Morgan et al. or Eckmayer et al. do not specifically disclose the limitation of a wet tear strength greater than 300 gf/mm, it would be reasonable for one of ordinary skill to recognize that this property would be present in the collagen product of Morgan et al. in view of Eckmayer et al. since Morgan et al. disclose an extruded porcine collagen product that meets the limitations of instant claim 1 (claim 17).

In their remarks, Applicants assert that (1) the disclosures of Morgan et al. discuss collagen casing prepared from porcine collagen derived from generally pig skins (p. 1 [0001]). While disclosures of Morgan et al. discuss changing properties of the casing by varying the ratio of porcine collagen derived from young pigs and older pigs (p. 2 [0019]), the disclosures of Morgan et al. are silent in regard to preparing a collagen film that has a collagen content that consists essentially of sow collagen. The disclosures of Eckmayer et al. discuss collagen membranes formed from porcine rinds (i.e. pig skins), particularly for wrapping food products (abstract). Eckmayer et al. are also silent in regard to preparing a collagen film that has a collagen content that consists essentially of sow collagen as instantly claimed. (2) Applicants again assert that as would be appreciated by one of ordinary skill in the art, the terms “casing” and “film” are quite different. The present application and Morgan et al. do not use these terms

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interchangeably. Applicant's arguments filed have been fully considered but they are not persuasive.

(1a) Applicants are directed to p. 15, claim 21, of Morgan et al., which discloses the porcine collagen can be derived from sow hides. On page 3 [0032], Morgan et al. disclose a general method of producing an extruded porcine collage film comprising removing fat, forming an extrudable gel, and extruding the gel to form a casing (p. 3 [0040]-0045]). Further, many of the working examples disclosed by Morgan et al. use sow hides (examples 3-12, 18, 21-22), which one of ordinary skill would know to substitute sow hides into the general method of producing an extruded porcine collagen film as disclosed on page 3 [0032], [0040]-[0045]).

(2a) Regarding the terms "casing" and "film"; this is still believed to be remedied by the Eckmayer et al. reference. Morgan et al. disclose an extruded collagen film (in the form of a tubular casing) made from an extrudable gel, wherein the collagen is sow collagen. Eckmayer et al. disclose extruded collagen membranes formed from porcine skins can be in the form of a film. It would be reasonable for one of ordinary skill to recognize that even if Morgan et al. do not explicitly disclose a working example of a porcine collagen film, the extruded collagen membrane of Morgan et al. can easily be formulated into a "film" for broader applications, i.e. to wrap around a ham or some other type of food product, since Eckmayer et al. disclose analogous extruded collagen membranes from porcine skins can have the form of a film. One of ordinary skill could easily see that extruded collagen membranes can have different physical forms, i.e. casing or film. A similar analogy would be a product being in the form of a lotion or a cream. Both lotion and cream are just different physical forms of the same product.

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Regarding Applicants' comments concerning Table 1, page 19 of the specification, this is not believed to be convincing due to Morgan et al.'s disclosure of using sow hides (or skins).

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 5, 2009